

### **REMARKS/ARGUMENTS**

Claims 15-17 and 21-36 are under examination in the application. Claims 16, 17 and 31 have been cancelled. The Final Office Action mailed on January 5, 2009, includes the following objections and rejections:

1. Claim 28 is objected to.
2. Claims 15-17 and 21-29 are rejected under 35 U.S.C. 112, first paragraph.
3. Claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a).

#### ***Claim Objections– Claims 28***

Applicant respectfully submits that claim 28 has been amended to overcome the objection and requests withdrawal of the objection.

#### ***Claim Objections– Claims 15-17 and 21-29 are rejected under 35 U.S.C. § 112, first paragraph.***

Applicant respectfully submits that the present application is enabled to support claims 15-17 and 21-29 as amended and fully complies with 35 U.S.C. § 112 first paragraph.

#### ***Claim Rejections – Claims 15-17 and 21-36 are rejected under 35 U.S.C. § 103(a)***

The Action also rejects claims 15-17 and 21-36 are rejected under 35 U.S.C. 103(a) as being as being unpatentable over Odie, et al. (Journal of Nutrition, 1991, Vol. 121, pages 605-614; provided by Applicant, hereafter referred to as “Odie”), in view of Ajinomoto (JP 52015834A (provided by Applicant) hereafter referred to as “Ajinomoto”) and Jandacek (US Patent No. 4,753,963 hereafter referred to as “Jandacek”). Applicant is fully aware of the above listed art as it was cited by the Applicants, and respectfully submit that the instant invention and

the combination of cited art are different and the instant inventions is not rendered obvious by the cited combination. The combination fails on all counts to establish obviousness.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

The Office Action has not met its burden to establish obviousness. The combination of Odie and Ajinomoto and Jandacek fails to teach a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a pharmaceutically effective amount of an isolated and purified n-heptanoic acid; triheptanoin; 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate, 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy-5-methylhexanoate, to treat the translocase deficiency wherein the compound is adapted for consumption in one or more doses of between 15 and 40% of the dietary caloric requirement for said infant for 24 hours to provide the infant nutrition from odd carbon fatty acid  $\beta$ -oxidation metabolism.

The combination fails to teach a pharmaceutically effective amount of an isolated and purified n-heptanoic acid and triheptanoin compositions to treat the translocase deficiency in a human infant. The combination fails to teach the specific compounds: 4-methylhexanoate, 4-

methylhexenoate, 3-hydroxy-4-methylhexanoate, 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy-5-methylhexanoate. The combination fails to disclose identifying an infant suspected of having a translocase deficiency and the combination fails to disclose administering to an infant suspected of having a translocase deficiency a composition.

In addition, the combination fails to provide a suggestion to modify the reference and fails to provide a reasonable expectation of success. There is nothing in the combination that teaches that the model systems are applicable to human infants with translocase deficiencies.

Accordingly, Applicants respectfully submit that claims are not obvious over the combination of Odle and Ajinomoto and Jandacek, and are, therefore, allowable under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection of claim be withdrawn.

### CONCLUSION

In light of the foregoing, Applicant submits that claims 15, 21-30 and 32-37 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. The Examiner is invited to call the undersigned at the below-listed telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: February 5, 2009.

Respectfully submitted,



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